K071243 pg 1 of 1

510(k) Summary
for the Metal Hemi Implant

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Metal Hemi Implant.

MAY 23 2007

Date Prepared: May 1, 2007

1. **Submitter:**
OrthoPro LLC
3450 Highland Dr. #303
Salt Lake City, UT 84106

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Metal Hemi Implant
Common Name: Hemi toe
Classification Name: prosthesis, toe, hemi-, phalangeal
Class II per 21 CFR section 888.3730
KWD

3. **Predicate or legally marketed devices which are substantially equivalent:**
OrthoPro Hemi toe (K062908) was modified resulting in the Metal Hemi Implant.

4. **Description of the device:**
The Metal Hemi Implant is a single stemmed resurfacing prosthesis for the first proximal phalanx designed to supplement first metatarsal phalangeal joint arthroplasty. The concave congruent articular surface has a mirror finish to minimize friction and matches the adjacent metatarsal head. The oval shape helps to reduce impingement on the metatarsal head, maintain range of motion and reduce pain without altering the joint biomechanics. The Metal Hemi Implant requires minimal bone resection and provides full range of motion of the first metatarsophalangeal joint (MPJ).

Materials:
The substrate of the Metal Hemi Implant is fabricated from CoCrMo alloy per ASTM F75
Plasma spray of commercially pure titanium per ASTM F67 is placed on the inferior surface and base of the stem of the implant

5. **Intended Use:**
The Metal Hemi Implant is a single stemmed resurfacing prosthesis for the first proximal phalanx designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidius, painful hallux valgus, revision of failed previous surgery and painful arthritis.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
The Metal Hemi Implant does not incorporate any new technological characteristics as compared to the predicate device. The Metal Hemi Implant and the predicate devices are made from the same material. The Metal Hemi Implant has the addition of CP Ti plasma spray.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OrthoPro LLC
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

MAY 23 2007

Re: K071243
Trade/Device Name: Metal Hemi Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: May 1, 2007
Received: May 3, 2007

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071243

Device Name: Metal Hemi Implant

Indications for Use:

The Metal Hemi Implant is designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidius, painful hallux valgus, revision of failed previous surgery and painful arthritis.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K071243